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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/830,905	08/08/2001	Ronald R. Breaker	OCR-794B.US	5301

7590 08/26/2003

Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C  
One Financial Center  
Boston, MA 02111

EXAMINER

MCGARRY, SEAN

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 08/26/2003

14

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 09/830,905	Applicant(s) BREAKER ET AL.	
	Examiner Sean R McGarry	Art Unit 1635	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE \_\_\_\_ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) ☒ Responsive to communication(s) filed on 02 May 2003.

2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4) ☒ Claim(s) 1-7 and 9-19 is/are pending in the application.

    4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.

5) ☐ Claim(s) \_\_\_\_ is/are allowed.

6) ☒ Claim(s) 1-7 and 9-19 is/are rejected.

7) ☐ Claim(s) \_\_\_\_ is/are objected to.

8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All   b) ☐ Some \* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) <input type="checkbox"/> Notice of References Cited (PTO-892) 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____ 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) 6) <input type="checkbox"/> Other:
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### DETAILED ACTION

Claims 1-7, 9, 10, 12-16 and 19 remain rejected under 35 U.S.C. 102(a) as being anticipated by Araki et al [Nucleic Acids Research Vol. 26(14): 3379-3384, 1998]. This rejection is maintained for the same reasons set forth in the Official Action mailed 1/2/03.

Claims 1-7, 9, 10, 12-16 and 19 remain rejected under 35 U.S.C. 102(b) as being anticipated by Tang et al [Chemistry and Biology Vol. 4(6): 453-459, 6/1997]. This rejection is maintained for the same reasons set forth in the Official Action mailed 1/2/03.

Claims 11, 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Araki et al., Tang et al., and Breaker [Chem. Rev. Vol. 97: 371-390, 1997]. This rejection is maintained for the same reasons set forth in the Official Action mailed 1/2/03.

Applicant's arguments filed 3/2/03 have been fully considered but they are not persuasive.

Applicant argues the above rejection with the assertion that by amending the claims to read "a randomized nucleotide sequence" in the bridging domain defines over the prior art. Applicant asserts that the prior art "bridging domain sequences" are all

"specifically designed" or "rationally designed" and are therefore not random as the claims are amended. The specification as filed does not provide a specific definition of what a randomized domain is in the context of the claim as now amended. The specification, for example, refers to the stem loop containing randomized domains for use in screening for functional bridging domains. See page 6, lines 4-6 and page 25, lines 5-13, where the context clearly shows that these random domains are referred to in the collection of ribozymes to be screened and not those selected. The domains of the prior art made and screened as in applicants screening methods would function as the ribozymes instantly claimed for example. If one were to randomly make a sequence as that taught in the art and screened as applicant specification teaches it would function. The "randomizing" itself is not what makes the domain function, for example. At page 13 of the instant specification it is stated that "[t]he molecular bridge in the engineered sensor is not passive, but is instead a functional communication module that activates. . . the action of the catalytic or reporter actuator." And at page 14 it is stated that a domain is "a functional designation, not a physical one. . ." It is noted that the context of the specification clearly intends the randomized sequence to be that of the pool of potential bridge sequences, for example. The limitation could clearly be interpreted to mean "a randomized bridging sequence which has been found to have the function screened for". In effect the limitation could, for example, be compared to a product by process limitation when the context of the limitation is read in light of the specification.

Furthermore although applicant argues that the domains of the prior are were specifically designed or rationally designed since they contain only A-U and G-C bonds, the art does not appear to specify what order or how many must be in the stems for a function, for example. Since See Figure 1 of Araki et al and Table 1 of Tang et al, for example). The prior art shows different combinations of A-U and G-C bonds in the various sized regions, for example. In this context the regions of the prior art could be considered random for this aspect, for example.

In addition to the above applicant also argues that the rejection under 35 USC 103 is deficient since the references since Breaker is drawn to randomized RNA pools. It is noted that applicant is putting the cart before the horse and arguing Breaker in view of Tang, for example. Tang cites Breaker as a source of a method of screening for improvements in what they (Tang et al) have taught. Clearly since Tang has taught the compounds of the invention (See 102 rejections above). The method of Breaker et al could be used to screen for improvements. All that the instant method requires is that the method is capable of screening for these compounds, for example. If these constructs are in a pool screened by the method of Breaker looking for compounds as taught by Tang et al they would be screened by the method.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

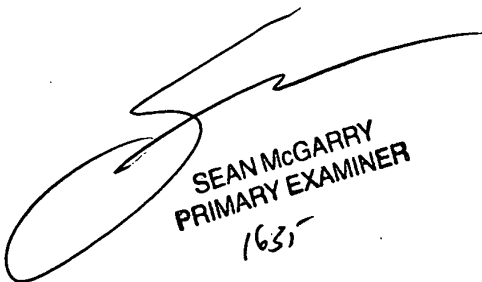
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean R McGarry whose telephone number is (703)305-7028. The examiner can normally be reached on M-Th (6:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on (703) 308-0447. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

SRM



SEAN MCGARRY  
PRIMARY EXAMINER  
1635-